

PREGTRIAL

QUARTERLY NEWSLETTER

DECEMBER 2025 - ISSUE #1

Welcome to the first edition of the
PregTrial Newsletter!



Our goals with
this newsletter
are to inform
you, engage with
you, and foster
continued
collaboration.

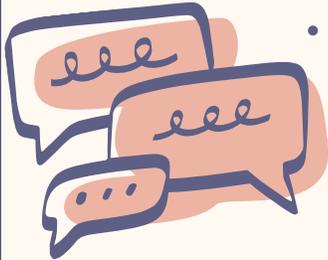
THIS ISSUE'S HIGHLIGHTS

- A new postdoctoral fellow has joined the team
- An informed Consent Form toolkit is being developed. We will be soliciting your input soon, so stay tuned!
- The Pregtrial team made meaningful contributions to the WHO Pregnant and lactating Women toolkit and the International Council for Harmonization (ICH) E21 guideline
- An exciting and engaging in-person PregTrial meeting is being planned for October 26-27, 2025
- 'Designing for Dyad's' paper is now published
- And more!

Progress & Milestones

INTERNATIONAL ENGAGEMENT

- **Participation in the WHO Global Clinical Trials Forum (GCTF):** We have initiated the process for PregTrial to represent the RI-MUHC in the WHO GCTF to collaborate on toolkits with the WHO's Pregnant and Lactating Women Task Force. The PregTrial team has made meaningful contributions to the WHO's task force on inclusion of pregnant and breastfeeding women in clinical trials disease agnostic toolkit.



- **Contribution to the International Council for Harmonization (ICH) E21 Public Consultation:** We hosted a webinar welcoming Health Canada members and the PregTrial community to solicit feedback for the E21 guideline. We submitted extensive feedback from that webinar to the ICH

on the draft E21 guideline. The final guideline will be ready in Q1 of 2028, at which point our goal will be dissemination to the Canadian audience for further implementation plans

NATIONAL ENGAGEMENT & COLLABORATIONS

- **Attendance at the IMPaCT Summit:** Our team joined national partners and experts at IMPaCT's 2025 summit November 17-19 in Toronto, learning from expert speakers, patient partner presentations, and IMPaCT research fellows.
- **Collaboration with CANREVIEW:** We are working with the CanReview team to support developing pregnancy friendly harmonized consent forms
- **Recent Publication:** Our paper '**Designing for Dyads**', a result of a collaboration between PregTrial and IMPaCT, is published. It outlines key action items including improved guidance, resources, tools, and training to support equitable perinatal trial participation and data sharing.
- **Evidence Scan:** The results of our evidence scan, done in collaboration with the **NCCMT** on the inclusion of pregnant & lactating women (P/LW) in vaccine trials, are live & on our website! This review showed that only 4% of trials that did not exclude P/LW took place in Canada & no trials including P/LW contributed to Health Canada vaccine approvals. A formal publication will hopefully be available in early 2026. We will engage with the communicable disease experts within PregTrial to contribute to this manuscript



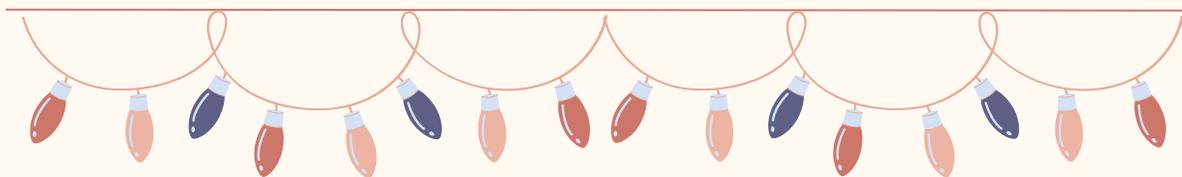
OTHER UPDATES

- **The website is live:** Visit us at www.pregtrial.ca - we will use this as a tool to share news, surveys and toolkits as they are developed
- **Our team is growing:** We are delighted to welcome our new postdoctoral fellow Rose Mwangi, PhD. Her bioethics expertise will be invaluable - welcome Rose!

COMING SOON!



- **We are developing an informed consent toolkit** using updated guidelines and frameworks to be used as tools for researchers considering including women of childbearing potential in clinical trials.
- **We are planning a mixed methods analysis** of researchers', patients' and REB members' knowledge, attitudes, and readiness to use tools supporting enhanced representation of pregnant and breastfeeding women
- **We are planning a PregTrial meeting** for October 26-27 2026 to gather knowledge holders to exchange expertise and develop consensus-based tools. keep an eye out for more updates which will be coming soon!



**HAPPY HOLIDAYS FROM THE PREGTRIAL
TEAM! WE WISH YOU A RESTFUL SEASON
AND LOOK FORWARD TO CONNECTING IN
THE NEW YEAR.**

STAY CONNECTED

Stay in touch with the PREGTRIAL team - contact us or visit our website for updates

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 www.pregtrial.ca